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Display Date 5-22-03
Publication Date 5-23-03
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0180]

Guidance for Industry and FDA; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile; Availability and a Request for Information From Such Manufacturers/ Processors

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry and FDA; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/ Processors With Interest in Exporting to Chile." This guidance explains that FDA intends to establish and maintain a list, which will be sent to Chile and posted on FDA's Internet site, identifying the names and addresses of U.S. manufacturers that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., injunction or seizure) or an unresolved warning letter.

DATES: This guidance is final upon the date of publication. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit electronic or written information for inclusion on the Chilean dairy list to Esther Z. Lazar, Center for Food Safety and Applied Nutrition (HFS–306) (see **FOR FURTHER INFORMATION CONTACT**). Send one self-

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addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. Submit written comments on the guidance document or the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments on the guidance document or the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance document.

Submit written requests for single copies of this guidance to the Office of Plant and Dairy Foods and Beverages, Division of Dairy and Egg Safety, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740.

FOR FURTHER INFORMATION CONTACT: Esther Z. Lazar, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1485, or e-mail: ELazar@CFSAN.FDA.GOV.

SUPPLEMENTARY INFORMATION:

I. Background

As a direct result of trade discussions that have been adjunct to the United States-Chile Free Trade Agreement, Chile has recognized FDA as the competent U.S. food safety authority and has accepted the U.S. regulatory system for dairy inspections. Chile has concluded that it will not require individual inspections of U.S. firms by Chile as a prerequisite for trade, but will accept firms

identified by FDA as eligible to export to Chile. Therefore, FDA intends to establish and maintain a list, which will be sent to Chile and posted on FDA's Internet site, identifying the names and addresses of U.S. dairy product manufacturers/processors that have expressed to FDA their interest in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or an unresolved warning letter. The term "dairy products," for purposes of this list, is not intended to cover the raw agricultural commodity raw milk.

II. Discussion

The guidance document states that FDA intends to establish and maintain a list identifying U.S. manufacturers/processors that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e. an injunction or seizure) or an unresolved warning letter. Inclusion of U.S. dairy product manufacturers/processors on this list is voluntary. However, dairy products from firms not on this list could be refused entry at the Chilean port of entry. The guidance explains what information firms should submit to FDA in order to be considered for inclusion on the list and what criteria FDA intends to use to determine eligibility for placement on the list. The document also explains how FDA intends to update the list and how FDA intends to communicate any new information to Chile. Finally, the guidance notes that FDA will consider the information on this list, which will be posted on FDA's Internet site and communicated to Chile, to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4).

This guidance represents the agency's current thinking on the procedures for assisting Chile in determining which U.S. manufacturers or processors are eligible to export dairy products to Chile. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

This guidance document is being issued as a level 1 guidance consistent with FDA's good guidance practices (GGPs) regulation (§ 10.115 (21 CFR 10.115)). Consistent with GGPs, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. The guidance document presents a less burdensome policy that is consistent with the public health.

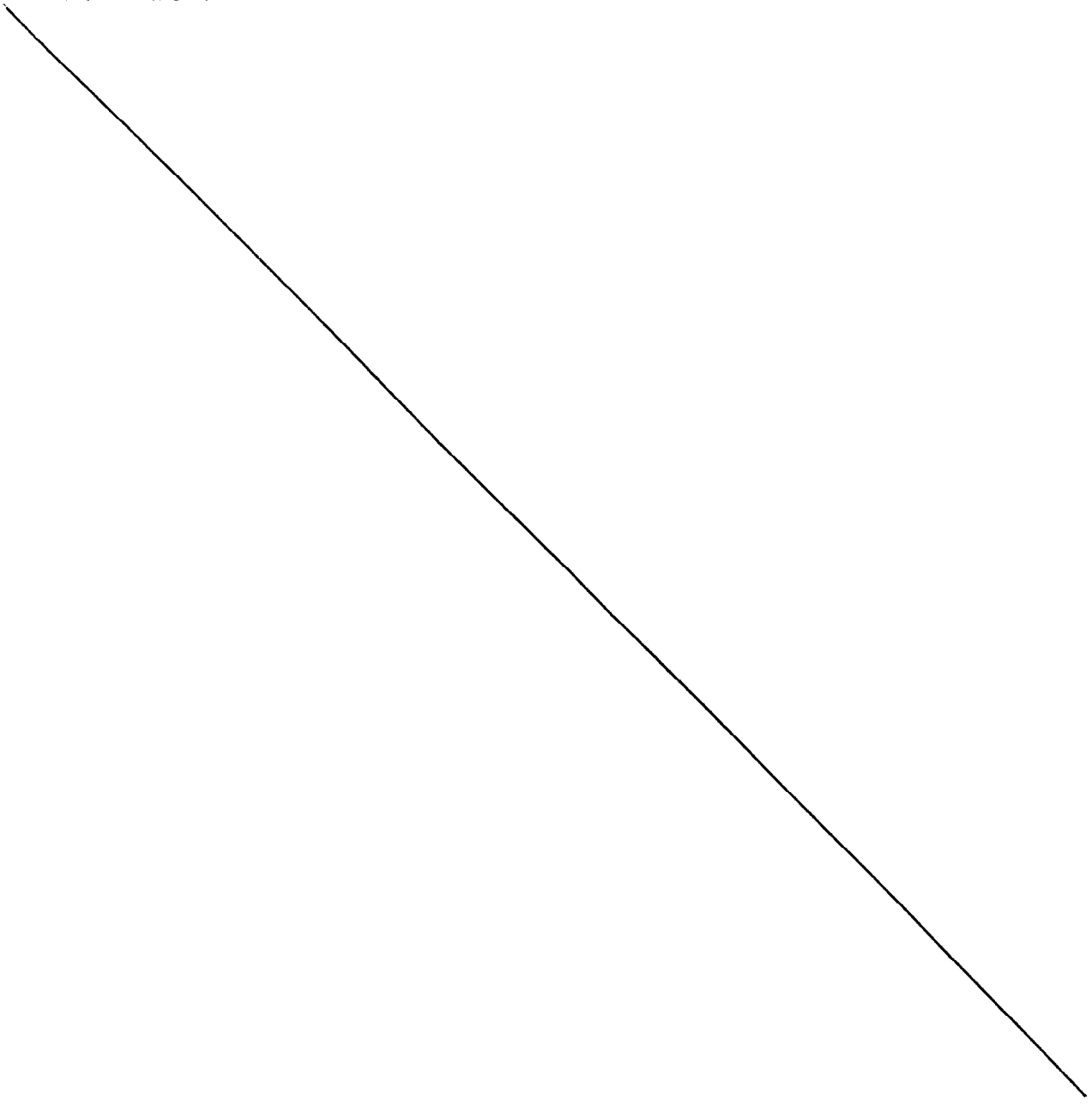
III. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

The Office of Management and Budget (OMB) has approved this collection of information under the emergency processing provision of the Paperwork

Reduction Act of 1995 (44 U.S.C. 3507(j) and 5 CFR 1320.13) and has assigned OMB control number 0910–0509. As discussed in the **Federal Register** of April 10, 2003 (68 FR 17655), public reporting burden for this collection of information is estimated to be 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.



V. Electronic Access

Interested persons also may access the guidance document at http://www.cfsan.fda.gov/guidance.html.

Dated: 5/15/03
May 15, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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